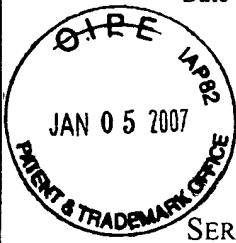


01-08-07

1654
TFC
Attorney Docket No.: 24492-013 NATL



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Antonio Cruz
SERIAL NUMBER: 10/535,745 EXAMINER : Christina Bradley
FILING DATE: November 17, 2005 ART UNIT : 1654
FOR: GASTRIN COMPOSITIONS AND FORMULATIONS, AND METHOD
OF USE AND PREPARATION

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER

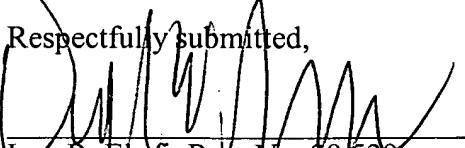
Transmitted herewith for filing in the present application are the following documents:

1. Information Disclosure Statement (1 page), in duplicate;
2. Modified Form 1449/PTO (5 pages), in duplicate;
3. Copies of Cited References: B1-16; C1-52;
4. Check in the amount of \$180.00 (#23602); and
5. Return Postcard.

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 542-6000, Boston, Massachusetts.

The Commissioner is authorized to charge any fees that may be due, or to credit any overpayment, to the undersigned's account, Deposit Account No. 50-0311 Ref. No. 24492-013 NATL. A duplicate copy of this transmittal letter is enclosed herewith.

Respectfully submitted,


Yvor R. Elriffi, Reg. No. 39,529
David E. Johnson, Reg. No. 41,874
Attorney(s) for Applicants
MINTZ, LEVIN, COHN, FERRIS,
GLOVSKY and POPEO, P.C.
Address all written correspondence to
Customer no.: 30623
Tel: (617) 542-6000
Fax: (617) 542-2241

Date: January 5, 2007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Antonio Cruz
SPECIAL NUMBER: 10/535,745 EXAMINER : Christina Bradley
FILING DATE: November 17, 2005 ART UNIT : 1654
FOR: GASTRIN COMPOSITIONS AND FORMULATIONS, AND METHOD
OF USE AND PREPARATION

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Applicants make of record the documents listed on the attached modified Form PTO-1449 (submitted in duplicate) in the above-identified application, copies of which are enclosed.

This Information Disclosure Statement is being filed after the mailing date of the first Office Action, but before the mailing date of either a final action under 37 C.F.R. §1.113 or a Notice of Allowance under 37 C.F.R. §1.311. By the waiver of 37 CFR 1.98(a)(2)(i) copies of the U.S. Patents A1-A12 and U.S. Published Applications A13-A24 are not submitted.

The fee of \$180.00 as set forth in 37 C.F.R. §1.17(p) is enclosed. Please charge any additional fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311 Reference No. 24492-013 NATL.

Date: January 5, 2007

Respectfully submitted,

David E. Johnson, Reg. No. 41,874

Attorney(s) for Applicants

MINTZ, LEVIN, COHN, FERRIS,
GLOVSKY and POPEO, P.C.

Address all written correspondence to

Customer no.: 30623

Tel: (617) 542-6000

Fax: (617) 542-2241

01/08/2007 SSITHIB1 00000030 10533745

01 FC:1806

-180.00 OP

01/08/2007 SSITHIB1 00000064 10535745

01 FC:1806

180.00 OP

Express Mail No.: EV 869861324 US
Date of Deposit: January 5, 2007

Page 1 of 5
Attorney Docket No.: 24492-013 NATL

Please type a plus sign (+) in this box

+

JAN 05 2007

Patent & Trademark Office

PTO/SB (12-97)

Approved for use through 9/30/00. OMB 0651-0031

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Modified Form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	10/535,745
		Filing Date	November 17, 2005
		First Named Inventor	Cruz
		Group Art Unit	1654
		Examiner Name	Christina Bradley
		Attorney Docket Number	24492-013 NATL

U.S. PATENT DOCUMENTS

Exam Initials	Cite No.	U.S. Patent Document No.	Issue Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date If Appropriate
	*A1	4,686,283	08/11/87	Nestor, Jr. et al.			
	*A2	4,760,023	07/26/88	Miyoshi et al.			
	*A3	4,997,950	03/05/91	Murphy et al.			
	*A4	5,041,533	08/20/91	Wunsch et al.			
	*A5	5,506,107	04/09/96	Cunningham et al.			
	*A6	5,837,460	11/17/98	Von Feldt et al.			
	*A7	5,885,956	03/23/99	Nardi et al.			
	*A8	6,288,301 B1	09/11/01	Nardi et al.			
	*A9	6,558,952 B1	05/06/03	Parikh et al.			
	*A10	6,899,883 B2	05/31/05	Dupre, John			
	*A11	6,989,148 B2	01/24/06	Dupre, John			
	*A12	7,037,504 B2	05/02/06	Magil et al.			

U.S. PUBLISHED APPLICATION DOCUMENTS

Exam Initials	Cite No.	U.S. Published Application No.	Published Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date If Appropriate
	*A13	2002/0072115	June, 2002	Harrison et al.			
	*A14	2002/0081285	June, 2002	Parikh et al.			
	*A15	2004/0023885	Feb., 2004	Brand et al.			
	*A16	2004/0037818	Feb., 2004	Parikh et al.			
	*A17	2004/0209801	Oct., 2004	Brand et al.			
	*A18	2004/0209816	Oct., 2004	Parikh et al.			
	*A19	2004/0229810	Nov., 2004	Cruz			
	*A20	2004/0266682	Dec., 2004	Cruz			
	*A21	2006/0183674	Aug., 2006	Brand et al.			
	*A22	2006/0189520	Aug., 2006	Brand et al.			
	*A23	2006/0234373	Oct., 2006	Brand et al.			
	*A24	2006/0234932	Oct., 2006	Brand, Stephen			

Express Mail No.: EV 869861324 US
Date of Deposit: January 5, 2007

Page 2 of 5
Attorney Docket No.: 24492-013 NATL

FOREIGN PATENT DOCUMENTS						
Exam Initials	Cite No.	Foreign Patent Document Office Number		Name of Patentee(s) or Applicant(s)	Date of Publication	Translation Yes No
	B1	EP	0 380 230 A2	APHTON CORPORATION	08/01/90	
	B2	WO	93/03757	CHIRON CORPORATION	03/04/93	
	B3	WO	95/19785	RESEARCH TRIANGLE PHARMACEUTICALS, LTD.	07/27/95	
	B4	WO	00/29438	MILLENNIUM PHARMACEUTICALS, INC.	05/25/00	
	B5	WO	00/44400	RTP PHARMA INC.; THER GENERAL HOSPITAL CORP.	08/03/00	
	B6	WO	01/39784 A1	THE GENERAL HOSPITAL CORP.	06/07/01	
	B7	WO	02/055152 A2	WARATAH PHARMACEUTICALS, INC.	07/18/02	
	B8	WO	03/040310 A2	WARATAH PHARMACEUTICALS, INC.	05/15/03	
	B9	WO	03/100024 A2	WARATAH PHARMACEUTICALS, INC.; UNIVERSITHY OF ALBERTA	12/04/03	
	B10	WO	03/103701 A1	WARATAH PHARMACEUTICALS, INC.	12/18/03	
	B11	WO	2004/037195 A2	WARATAH PHARMACEUTICALS, INC.	05/06/04	
	B12	WO	2004/045640 A1	WARATAH PHARMACEUTICALS, INC.	06/03/04	
	B13	WO	2004/096853 A1	WARATAH PHARMACEUTICALS, INC.	11/11/04	
	B14	WO	2004/105780 A2	WARATAH PHARMACEUTICALS, INC.	12/09/04	
	B15	WO	2005/072045 A2	WARATAH PHARMACEUTICALS, INC.	08/11/05	
	B16	WO	2006/002532 A1	WARATAH PHARMACEUTICALS, INC.	01/12/06	
OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS						
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.				
	C1	Aly et al., "Short term infusion of glycine-extended gastrin ₁₇ stimulates both proliferation and formation of aberrant crypt foci in rat colonic mucosa", <i>Int. J. Cancer</i> , 94:307-313 (2001)				
	C2	Aly et al., "Gastrins, cholecystokinins and gastrointestinal cancer", <i>Biochimica et Biophysica Acta</i> , 1704:1-10 (2004)				
	C3	Anderson et al., "The human plasma proteome: history, character, and diagnostic prospects", <i>Mol. Cell. Proteomics</i> , 1:845-867 (2002)				
	C4	Baggio et al., "Sustained expression of exendin-4 does not perturb glucose homeostasis, β-cell mass, or food intake in metallothionein-preproexendin transgenic mice", <i>J. Biol. Chem.</i> , 275(44):34471-34477 (2000)				
	C5	Behr et al., "Radiolabeled peptides for targeting cholecystokinin-B/gastrin receptor-expressing tumors", <i>J. Nucl. Med.</i> , 40:1029-1044 (1999)				
	C6	Boniface et al., "Clearance rate, half-life, and secretory potency of human gastrin-17-I in different species", <i>Gastroenterol.</i> , 71:291-294 (1976)				
	C7	Brelje et al., "The physiological roles of prolactin, growth hormone and placental lactogen in the regulation of islet β cell proliferation", <i>Pancreatic Growth Regen.</i> , Chapter 1, pp. 1-30 (1997)				
	C8	Carlsson et al., "Protein thiolation and reversible protein-protein conjugation", <i>Biochem. J.</i> , 173:723-737 (1978)				
	C9	Carpenter et al., "The epidermal growth factor family", Chapter 4, pp. 69-171 (1990)				

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
	C10	Crean et al., "Parietal cell hyperplasia induced by the administration of pentagastrin (ICI 50,123) to rats", <i>Gastroenterol.</i> , 57(2):147-155 (1969)
	C11	Cunningham et al., "Receptor and antibody Epitopes in human growth hormone identified by homolog-scanning mutagenesis", <i>Science</i> , 243:1330-1336 (1989)
	C12	Cunningham et al., "High-resolution Epitope mapping of hGH-receptor interactions by alanine-scanning mutagenesis", <i>Science</i> , 244:1081-1085 (1989)
	C13	Dockray et al., "Immunochemical characterization of gastrin pancreatic islets of normal and genetically obese mice", <i>J. Endocrinol.</i> , 72:143-151 (1977)
	C14	Dockray et al., "Postsecretory processing of heptadecapeptide gastrin: conversion to C-terminal immunoreactive fragments in the circulation of the dog", <i>Gastroenterol.</i> , 83(1):224-232 (1982)
	C15	Dockray, G.J., "Topical review. Gastrin and gastric epithelial physiology" <i>J. Physiol.</i> , 518(pt.2):315-324 (1999)
	C16	Drucker, D.J., "Minireview: the glucagon-like peptides", <i>Endocrinol.</i> , 142(2):521-529 (2001)
	C17	Elbrønd et al., "Pharmacokinetics, pharmacodynamics, safety, and tolerability of a single-dose of NN2211, a long-acting glucagon-like peptide 1 derivative, in healthy male subjects", <i>Diabetes Cure</i> , 25:1398-1404 (2002)
	C18	Felix A.M., "Site-specific poly(ethylene glycol)ylation of peptides", <i>Chemistry and Biological Applications</i> , Chapter 16, pp. 218-238 (1997)
	C19	García-Ocaña et al., "Using β-cell growth factors to enhance human pancreatic islet transplantation", <i>J. Clin. Endocrinol. Metab.</i> , 86(3):984-988 (2001)
	C20	Goeddel et al., "Direct expression in Escherichia coli of a DNA sequence coding for human growth hormone", <i>Nature</i> , 281:544-548 (1979)
	C21	Gray et al., "Periplasmic production of correctly processed human growth hormone in Escherichia coli: natural and bacterial signal sequences are interchangeable", <i>Gene</i> , 39:247-254 (1985)
	C22	Hughes et al., "NVP-LAF237, a highly selective and long-acting dipeptidyl peptidase IV inhibitor", <i>Abstract 272-OR</i> , page A67 (2002)
	C23	Ito et al., "Structural analysis of the gene encoding human gastrin: the large intron contains an Alu sequence", <i>Proc. Natl. Acad. Sci. USA</i> , 81:4662-4666 (1984)
	C24	Koffman et al., "Effect of urogastrone on gastric secretion and serum gastrin concentration in patients with duodenal ulceration", <i>Gut</i> , 23:951-956 (1982)
	C25	Lima-Leite et al., "Synthesis and biological activities of some human gastrin analogs", <i>Braz. J. Med. Biol. Res.</i> , 29:1253-1263 (1996)
	C26	Lin et al., "A71378: a CCK agonist with high potency and selectivity for CCK-A receptors", <i>Am. J. Physiol.</i> , 258(4-pt.1):G648-G651 (1990)
	C27	Lin et al., "Introduction of sulfhydryl groups into proteins at carboxyl sites", <i>Biochimica et Biophysica Acta</i> , 1038:382-385 (1990)
	C28	Mode et al., "The human growth hormone (hGH) antagonist ^{G120R} hGH does not antagonize GH in the rat, but has paradoxical agonist activity, probably via the prolactin receptor", <i>Endocrinol.</i> , 137(2):447-454 (1996)

	C29	Nauck et al., "Additive insulinotropic effects of exogenous synthetic human gastric inhibitory polypeptide and glucagon-like peptide-1-(7-36) amide infused at near-physiological insulinotropic hormone and glucose concentrations", <i>J. Clin. Endocrinol. Metab.</i> , 76(4):912-917 (1993)
	C30	Nielsen et al., "Beta cell proliferation and growth factors", <i>J. Mol. Med.</i> , 77:62-66 (1999)
	C31	Ørskov et al., "Tissue and plasma concentrations of amidated and glycine-extended glucagon-like peptide I in humans", <i>Diabetes</i> , 43:335-339 (1994)
	C32	Pedersen et al., "Reactivity of the thiol group in human and bovine albumin at pH 3-9, as measured by exchange with 2,2'-dithiodipyridine", <i>Eur. J. Biochem.</i> , 106:291-295 (1980)
	C33	Rehfeld et al., "The effect of gastrin on basal- and glucose-stimulated insulin secretion in man", <i>J. Clin. Invest.</i> , 52:1415-1426 (1973)
	C34	Rehfeld et al., "The effect of gastrin and cholecystokinin on the endocrine pancreases", <i>Front. Hormone Res.</i> , 7:107-118 (1980)
	C35	Rehfeld, J.F., "The new biology of gastrointestinal hormones", <i>Physiol. Rev.</i> , 78(40):1087-1108 (1998)
	C36	Rooman et al., "Effects of gastrin on proliferation and differentiation in regenerating pancreas", <i>Diabetologia, Abstract</i> , (2000)
	C37	Rooman et al., "Gastrin stimulates β -cell neogenesis and increases islet mass from transdifferentiated but not from normal exocrine pancreas tissue", <i>Diabetes</i> , 51:686-690 (2002)
	C38	Ryberg et al., "Trophic effects on continuous infusion of [Leu ¹⁵]-gastrin-17 in the rat", <i>Gastroenterol.</i> , 98:33-38 (1990)
	C39	Sandvik et al., "Biological activity of carboxy-terminal gastrin analogs", <i>Eur. J. Pharmacol.</i> , 364:199-203 (1999)
	C40	Sasaki et al., "Dietary docosahexaenoic acid can alter the surface expression of CD4 and CD8 on T cell in peripheral blood", <i>J. Agric. Food Chem.</i> , 48:1047-1049 (2000)
	C41	Sigma, "G9145 [Leu ¹⁵]-gastrin I human", http://www.sigmaaldrich.com/catalog/search/ProductDetail/SIGMA/G9145 , (2006)
	C42	Sigma, "G7264 big gastrin I human", https://www.sigmaaldrich.com/catalog/search/ProductDetail/SIGMA/G7264 , (2006)
	C43	Slice et al., "Gastrin and EGF synergistically induce cyclooxygenase-2 expression in Swiss 3T3 fibroblasts that express the CCK ₂ receptor", <i>J. Cell. Physiol.</i> , 196:454-463 (2003)
	C44	Taylor et al., "Effect of individual L-amino acids on gastric acid secretion and serum gastrin and pancreatic polypeptide release in humans", <i>Gastroenterol.</i> , 83:273-278 (1982)
	C45	Thanou et al., "Polymer-protein and polymer-drug conjugate in cancer therapy", <i>Curr. Opin. Investig. Drugs</i> , 4(6):701-709 (2003)
	C46	Tracy et al., "Physiological properties of a series of synthetic peptides structurally related to gastrin 1", <i>Nature</i> , 204:935--938 (1964)
	C47	Vergelli et al., "Immunosuppressive activity of 13-cis-retinoic acid in rats: aspects of pharmacokinetics and pharmacodynamics", <i>Immunopharmacol.</i> , 37:191-197 (1997)
	C48	Veronese, F.M., "Peptide and protein PEGylation: a review of problems and solutions", <i>Biomaterials</i> , 22:405-417 (2001)
	C49	Wang et al., "Function and regulation of gastrin in transgenic mice: a review", <i>Yale J. Biol. Med.</i> , 65:705-713 (1992)

Express Mail No.: EV 869861324 US
Date of Deposit: January 5, 2007

Page 5 of 5
Attorney Docket No.: 24492-013 NATL

	C50	Wang et al., "Pancreatic gastrin stimulates islet differentiation of transforming growth factor α -induced ductular precursor cells", <i>J. Clin. Invest.</i> , 92:1349-1356 (1993)
	C51	Winer et al., "Autoimmune islet destruction in spontaneous type 1 diabetes is not β -cell exclusive", <i>Nat. Med.</i> , 9(2):198-205 (2003)
	C52	Yoshitake et al., "Conjugation of glucose oxidase from aspergillus niger and rabbit antibodies using N-hydroxysuccinimide ester of n-(4-carboxycyclohexylmethyl)-maleimide", <i>Eur. J. Biochem.</i> , 101:395-399 (1979)

* By the waiver of 37 CFR 1.98(a)(2)(i) copies of the U.S. Patents A1-A12 and U.S. Published Applications A13-A24 are not submitted.

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

TRA 2239584v.1